JUL 26 2006

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510(k) SUMMARY

The following 510(k) summary is being submitted as required by 21 CFR 807.92(a):

Submission Information

Sponsor:	BK MEDITECH Co., Ltd. 215-5 Yodang-Li, Yanggam-Myun, Hwasung-Si, Kyunggi-Do, Republic of Korea
Manufacturing Site	BK MEDITECH Co., Ltd. 215-5 Yodang-Li, Yanggam-Myun, Hwasung-Si, Kyunggi-Do, Republic of Korea
US Agent:	Henry Yang 25041, Farrier Circle, Laguna Hills, CA 92653
Official Correspondent:	Byungjun Park 215-5 Yodang-Li, Yanggam-Myun, Hwasung-Si, Kyunggi-Do, Republic of Korea

Device Identification

Proprietary Name:	Pin Screw
Common/Usual Name:	Fixation Pin
Classification Name:	Smooth or threaded metallic bone fixation fastener per 21 CFR § 888.3040
Product Code:	JDW

Substantially Equivalent Predicate Legally Marketed Devices

The subject device, Pin Screw, is substantially equivalent in function, design, composition, material and intended used to:

Apex Fixation Pins(K011136)

Device Description

The Pin Screws have a tapered thread diameter and are available in a variety of diameter and lengths in both cortical and cancellous thread patterns. The Pin Screws will be available with and without the additional proprietary self-drilling on the threads.

The Pin Screws are manufactured from surgical grade stainless steel, 316L per

ASTM F138.

The Pin Screws are inserted into the bone nearest the fracture site and connected externally to a rigid external supporting frame for immobilization of unstable fractures

The Pin Screws are provided non-sterile and must be cleaned and sterilized prior to use according to the procedures outlined in this document.

Indications for Use

The Pins are intended to be used in conjunction with a rigid external supporting frame for immobilization of open and/of unstable fractures and where the soft tissue injury may preclude the use of other fracture treatments such as IM rodding, casting and other means of internal fixation.

Comparison to Legally Marketed Predicate Device

The technological characteristics are the same as or equivalent to the predicate device previously listed.

Therewith, the Pin Screw is manufactured from 316L stainless steel which is identical to all of the identified predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 26 2006

BK Meditech Co., Ltd.
% Mr. Byungjun Park
Manager
215-5 Yodang-Li, Yanggam-Myun
Hwasung-si, Kyunggi-do 445-931
Republic of Korea

Re: K061599
Trade/Device Name: Pin Screw
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: II
Product Code: JDW
Dated: June 5, 2006
Received: June 9, 2006

Dear Mr. Park:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Barbara Bruens

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K061599

Device Name: **Pin Screw**

Indications for Use:

The Pins are intended to be used in conjunction with a rigid external supporting frame for immobilization of open and/of unstable fractures and where the soft tissue injury may preclude the use of other fracture treatments such as IM rodding, casting and other means of internal fixation.

Prescription Use ✓ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number BK MEDITECH CO.,LTD. K061599

Pin Screw